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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,705	11/07/2000	Kenji Sakamoto	IKU0104PUSA	2404

7590

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/647,705

Applicant(s)

SAKAMOTO, KENJI

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) (Paper NO. 15) filed on October 22, 2002. The request for RCE is accepted and is established with the status of the application as follows:
  - a. the filling date of this RCE is established as 11/7/2000;
  - b. Claims 1-4, 18 are pending. New claims 19-22 are added.
2. Upon expiration of the Applicant's request for suspending the action for 3 months (Paper No. 15), the instant case is opened for prosecution herein.
3. Applicants' response to the earlier office action (Paper No. 13) filed on July 22, 2002 is reconsidered and has been entered.

**Response to Arguments**

4. Applicant's response to the office action (Paper No.13) is fully considered and found persuasive in view of arguments.
5. With reference to the rejection maintained in the previous office action under 35 U.S.C. 112 first and second paragraphs, Applicants' arguments and amendment have been fully considered and the rejection is withdrawn in view of the amendment.
6. With reference to the rejection maintained in the previous office action under 35 U.S.C. 102(b), applicants' arguments and amendment have been fully considered and found persuasive. The argument is fully considered and the rejection is moot in view of the new grounds of rejection.
7. With reference to the rejection maintained in the previous office action under 35 U.S.C. 103(a), applicants' arguments and amendment have been fully considered and found persuasive

The argument is fully considered and the rejection is moot in view of the new grounds of rejection.

### **New Grounds of Rejections**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

Here, the new limitation of "as a stand-alone peptide irrespective of its activity as part of a receptor" in the claim 1 appears to represent new matter. A careful review by examiner of the specification, this phrase was not present. Thus the phrase "as a stand-alone peptide irrespective of its activity as part of a receptor" lacks descriptive support in the specification.

Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsson et al. (USPN. 6,333,031) and in view of Narada et al. (Proc.Natl.Acad.Sci. USA, Vol. 94, pp. 11692-11697, 1997).

Olsson et al. teach a method for determining and producing biologically active peptides wherein Olsson et al. disclose that the method comprises receptor variants having activation sequence, and differ in size as compared to a known receptor sequence of interest (see column 12, lines 29-67, and column 13, lines 1-48, column 23, lines 34-64), the receptors being receptive of an identical ligand and being products of the same gene, wherein a substance (drug) acts as on the ligand for the receptor (see column 20, lines 25-36); identifying missing region (activation sequence) in shorter peptides and determining the missing sequence as a domain having physiological activity of that peptide (see column 20, lines 37-65, column 23, lines 34-64). Olsson et al. also teach derived peptides have at least 60-98% identical to the activation sequence (missing region) of the receptor (see column 13, lines 49-62); the missing region could be chemically synthesized (column 15, lines 7-19, column 29, lines 15-25). However Olsson et al. did not teach a substance or cell present in vivo (endogenous) acting as an antagonist to the said ligand.

Narada et al. teach insulin-like receptor peptides and its variants having shorter sequences and their effect in binding and bioactivity (see page 11695, column 1, paragraph 1-2), wherein Narada et al. teach that the ligand-dependent internalization of the deletion mutant substantially

reduce endogenous substance (insulin or glucose uptake) as compared to the wild type (see page 11695, column 2, paragraph 6-7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of identifying receptor variants as taught by Olsson et al. with an antagonist activity as taught by Narada et al. to achieve an expected advantage of developing a method for identifying physiologically active peptides because Narada et al. states that "recognition of specific sequence on insulin receptor suggests ligand-dependent IR internalization and its mechanism affecting endocytosis"(see page 11695, column 2, paragraph 7). An ordinary practitioner would have been motivated to combine the teachings of Olsson et al. with Narada et al. to develop a sensitive method for identifying physiologically active receptor peptides by adding the limitations as taught by Narada et al. because such limitations would increase the specificity of the binding of the peptide to the ligand.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru

April 15, 2003



JEFFREY FREDMAN  
PRIMARY EXAMINER